

1 RAYMOND M. WILLIAMS (Bar No. 164068)  
2 raymond.williams@dlapiper.com  
3 DLA PIPER LLP (US)  
4 1650 Market Street, Suite 4900  
Philadelphia, PA 19103  
Tel: 215.656.3300  
Fax: 215.656.3301

5 CHRISTOPHER M. YOUNG (Bar No. 163319)  
6 christopher.young@dlapiper.com  
7 DLA PIPER LLP (US)  
401 B Street, Suite 1700  
San Diego, CA 92101  
Tel: 619.699.2700  
Fax: 619.699.2701

9 LOREN H. BROWN  
10 loren.brown@dlapiper.com  
HEIDI LEVINE  
11 heidi.levine@dlapiper.com  
DLA PIPER LLP (US)  
12 1251 Avenue of the Americas, 27th Floor  
New York, NY 10020-1104  
Tel: 212.335.4500  
13 Fax: 212.335.4501

14 Attorneys for Defendant  
15 NOVO NORDISK INC.

16 **UNITED STATES DISTRICT COURT**  
17 **SOUTHERN DISTRICT OF CALIFORNIA**

18 IN RE INCRETIN-BASED  
19 THERAPIES PRODUCTS  
20 LIABILITY LITIGATION

21 *This Document Relates to All Cases*

Case No. 3:13-MD-02452-AJB-MDD

**DECLARATION OF HEIDI LEVINE  
IN SUPPORT OF DEFENDANT  
NOVO NORDISK INC.'S MOTION  
TO STRIKE FROM THE PUBLIC  
DOCKET OR, IN THE  
ALTERNATIVE, TO SEAL  
PLAINTIFFS' EXPERT REPORTS  
REGARDING PREEMPTION**

Judge: Hon. Anthony J. Battaglia

1 I, Heidi Levine, declare as follows:

2 1. I am an attorney with DLA Piper LLP (US), counsel for Defendant  
3 Novo Nordisk Inc. (“NNI”). I am licensed to practice in the State of New York. I  
4 have personal knowledge of the facts set forth herein. I submit this declaration in  
5 support of the Motion to Strike from the Public Docket or, in the Alternative, to  
6 Seal Plaintiffs’ Expert Reports Regarding Preemption.

7 2. Several sections of Dr. Fleming’s expert report (the “Fleming Report”)  
8 discuss NNI’s confidential and proprietary information and as demonstrated below,  
9 good cause exists to seal these confidential documents and the sections of the  
10 Fleming Report discussing the content of these documents.

11 3. The confidential sections of the Fleming Report that NNI seeks leave  
12 to maintain under seal are set forth below, in detail:

13 a. **Fleming Report, p. 40, para. 4, No. 2:** In this paragraph,  
14 Dr. Fleming incorporates confidential data from a draft internal slide presentation  
15 relating to clinical trials for NNI’s obesity medication. This document was properly  
16 designated by NNI as confidential under the Protective Order in this case because it  
17 contains internal discussions regarding safety analysis and methodologies regarding  
18 the FDA Advisory Committee Meeting for NNI’s obesity medication. This  
19 document also contains an internal stamp of “CONFIDENTIAL” and a legend  
20 restricting its use and disclosure. Releasing this information to the public or co-  
21 Defendants would allow competitors to benefit from the proprietary research and  
22 methods developed by NNI.

23 b. **Fleming Report, p. 41, para. 2, No. 4:** In this paragraph, Dr.  
24 Fleming incorporates proprietary data, internal analysis, and results of the same  
25 internal nonclinical study involving liraglutide and exenatide discussed below in  
26 Paragraph 3.c., and which was properly designated by NNI as confidential under  
27 the Protective Order in this case. This document also contains an internal stamp of  
28 “DRAFT” and “INTERNAL USE ONLY.” Releasing this information to the

1 public or co-Defendants would allow competitors to benefit from the proprietary  
2 research and methods developed by NNI.

3           c.     **Fleming Report, p. 60, para. 1 relating to footnote 146**  
4 **(Knudsen Deposition p. 134:6-137:11):** In this paragraph, Dr. Fleming  
5 incorporates methodologies and conclusions from the October 2, 2014 deposition  
6 testimony of Dr. Lotte Knudsen, which were properly designated by NNI as  
7 confidential under the Protective Order in this case and which relate to NNI's  
8 confidential and proprietary data, internal analysis, and results of an internal  
9 nonclinical study involving liraglutide and exenatide, a competitor product.  
10 Releasing this information to the public or co-Defendants would allow competitors  
11 to benefit from the proprietary research and methods developed by NNI.

12           d.     **Fleming Report, p. 61, para. 3 relating to footnotes 148 and**  
13 **149 (NOVO-02278271-96):** In this paragraph, Dr. Fleming incorporates  
14 information from a document properly designated as confidential under the  
15 Protective Order in this case, which relates to NNI's internal analysis of lipase  
16 study data. The information contained in this document reflects internal research  
17 results not released to NNI's competitors. Releasing this information to the public  
18 or co-Defendants would allow competitors to benefit from the proprietary research  
19 and methods developed by NNI.

20           e.     **Fleming Report, p. 61, para. 3 relating to footnotes 148 and**  
21 **150 (NOVO-02348487-539):** In this paragraph, Dr. Fleming incorporates  
22 proprietary data, internal analysis, and results of the same internal nonclinical study  
23 involving liraglutide and exenatide discussed above in Paragraph 3.a., and which  
24 was properly designated by NNI as confidential under the Protective Order in this  
25 case. This document also contains an internal stamp of "DRAFT" and "INTERNAL  
26 USE ONLY." Releasing this information to the public or co-Defendants would  
27 allow competitors to benefit from the proprietary research and methods developed  
28 by NNI.

1                   f.       **Fleming Report, p. 61, para. 3 and footnote 151 (Knudsen**  
2 **Deposition p. 159:19-160:6):** In this paragraph, Dr. Fleming incorporates facts,  
3 conclusions, and a direct quotation from deposition testimony properly designated  
4 by NNI as confidential under the Protective Order in this case and which relate to  
5 NNI's proprietary data, analysis, and results of an internal nonclinical study  
6 involving liraglutide and exenatide discussed above in Paragraph 3.a. Releasing  
7 this information to the public or co-Defendants would allow competitors to benefit  
8 from the proprietary research and methods developed by NNI.

9                   g.       **Fleming Report, p. 65, para. 2 relating to footnote 158**  
10 **(NOVO-00948679-9386):** In this paragraph and footnote, Dr. Fleming  
11 incorporates details from an August 23, 2013 Addendum to Clinical Overview,  
12 properly designated by NNI as confidential under the Protective Order in this case,  
13 and provides details concerning NNI's internal analysis of adverse event data from  
14 recent clinical studies. This document, also cited by Dr. Fleming in footnote 231,  
15 was properly designated by NNI as confidential under the Protective Order in this  
16 case because it discusses internal pharmacovigilance and safety analyses, contains  
17 an internal stamp of "CONFIDENTIAL" and a legend restricting its use and  
18 disclosure. Releasing this information to the public or co-Defendants would allow  
19 competitors to benefit from the proprietary research and analytical methods  
20 developed by NNI.

21                   h.       **Fleming Report, p. 65, para. 2 and footnote 159 (NOVO-**  
22 **00118902-77 and NOVO-00264339-5451):** In this paragraph and footnote, Dr.  
23 Fleming incorporates confidential details concerning NNI's internal analysis of  
24 adverse event data from recent clinical studies. One of the source documents,  
25 NNI's White Paper, which is the same document referenced by Dr. Fleming in  
26 footnotes 195, 202, and 203, was properly designated by NNI as confidential under  
27 the Protective Order in this case because it discusses internal pharmacovigilance  
28 and safety analyses, contains an internal stamp of "CONFIDENTIAL" and a legend

1 restricting its use and disclosure. The second document cited in this footnote,  
2 Development Safety Update Report (“DSUR”) No. 1, also contains an internal  
3 stamp of “CONFIDENTIAL” and a legend restricting its use and disclosure.  
4 Further, like Periodic Safety Update Reports, DSURs are confidential. Releasing  
5 this information to the public or co-Defendants would allow competitors to benefit  
6 from the proprietary research and methods developed by NNI.

7           i.       **Fleming Report, p. 65, para. 3 relating to footnote 160**  
8 **(NOVO-01518117-80):** In this paragraph and footnote, Dr. Fleming incorporates  
9 confidential data from a draft internal slide presentation relating to clinical trials for  
10 NNI’s obesity medication. This document was properly designated by NNI as  
11 confidential under the Protective Order in this case because it contains internal  
12 discussions regarding safety analysis and methodologies regarding the FDA  
13 Advisory Committee Meeting for NNI’s obesity medication. This document also  
14 contains an internal stamp of “CONFIDENTIAL” and a legend restricting its use  
15 and disclosure. Releasing this information to the public or co-Defendants would  
16 allow competitors to benefit from the proprietary research and methods developed  
17 by NNI.

18           j.       **Fleming Report, p. 78, para. 3 relating to footnote 195**  
19 **(NOVO-00118902-77):** In this paragraph, Dr. Fleming incorporates confidential  
20 details concerning NNI’s ongoing, proprietary clinical studies. This document,  
21 NNI’s White Paper, which is the same document referenced by Dr. Fleming in  
22 footnotes 159, 202, and 203, was properly designated by NNI as confidential under  
23 the Protective Order in this case. Releasing this information to the public or co-  
24 Defendants would allow competitors to benefit from the proprietary research and  
25 methods developed by NNI.

26           k.       **Fleming Report, p. 79, para. 3 and p. 80, para. 1 relating to**  
27 **footnote 200 (NOVO-01022167-541):** In these paragraphs and footnote, Dr.  
28 Fleming describes confidential details of an ongoing, proprietary study of

1 liraglutide. This document, properly designated by NNI as confidential under the  
2 Protective Order in this case, also contains an internal stamp of  
3 “CONFIDENTIAL” and a legend restricting its use and disclosure. Releasing this  
4 information to the public or co-Defendants would allow competitors to benefit from  
5 the proprietary research and methods developed by NNI.

6           1.     **Fleming Report, p. 80, para. 2 relating to footnotes 202 and**  
7 **203 (NOVO-00118902-77 and NOVO-02153958-4002):** In this paragraph and  
8 footnotes, Dr. Fleming describes confidential details of an ongoing, proprietary  
9 study of liraglutide. One of the source documents, NNI’s White Paper, which is  
10 the same document cited by Dr. Fleming in footnotes 159 and 195 was properly  
11 designated by NNI as confidential under the Protective Order in this case, contains  
12 an internal stamp of “CONFIDENTIAL” and also contains a legend restricting its  
13 use and disclosure. The other source document, a proprietary interim study report,  
14 has a “RESTRICTED” designation and was marked confidential under the  
15 Protective Order in this case. Releasing this information to the public or co-  
16 Defendants would allow competitors to benefit from the proprietary research and  
17 methods developed by NNI.


18           m.     **Fleming Report, p. 82, para. 2 relating to footnote 207**  
19 **(NOVO-00949394-5):** In this paragraph, Dr. Fleming includes details about  
20 confidential regulatory correspondence with the EMA concerning liraglutide. NNI  
21 properly designated this document as confidential under the Protective Order in this  
22 case. Releasing this information to the public or co-Defendants would allow  
23 competitors to benefit from the proprietary research and methods developed by  
24 NNI.

25           n.     **Fleming Report, p. 94, para. 1 relating to footnote 231**  
26 **(NOVO-00948679-9386):** In this paragraph, Dr. Fleming incorporates data from  
27 an August 23, 2013 Addendum to Clinical Overview, providing details about its  
28 content which describe NNI’s internal analysis of adverse event data from recent

1 clinical studies, and properly designated by NNI as confidential under the  
2 Protective Order in this case. This document also cited by Dr. Fleming in footnote  
3 158, contains an internal stamp of "CONFIDENTIAL" and a legend restricting its  
4 use and disclosure. Releasing this information to the public or co-Defendants  
5 would allow competitors to benefit from the proprietary research and analytical  
6 methods developed by NNI.

7 I declare under penalty of perjury under the laws of the United States that  
8 the foregoing is true and correct.

9 Executed on January 6, 2015 in the State of New York.

10  
11   
12 Heidi Levine